

C'ent phosphate ions and/or source of electrolytes necessary to maintain physiological function selected from  $\text{Na}^+$ ,  $\text{K}^+$ ,  $\text{Ca}^{2+}$  and  $\text{Cl}^-$ .

C<sup>2</sup> 11. (Thrice Amended) An aqueous ocular irrigating solution for irrigating the eye during surgery consisting essentially of a source of bicarbonate ions, a physiologically acceptable organic buffer which is an organic zwitterionic buffer having a buffering capacity within the range pH 6.8 to 8.0, sources of electrolytes necessary to maintain physiological function and optionally a source of phosphate ions selected from  $\text{Na}^+$ ,  $\text{K}^+$ ,  $\text{Ca}^{2+}$  and  $\text{Cl}^-$ , and wherein the bicarbonate source is present in the solution to give a bicarbonate concentration of from 10 to 50 mmol/l.

### REMARKS

Claims 1-19 are pending in the application. Amendments to claims 1 and 11 have submitted for entry after final. Support for the claim amendments is found generally at page 4, lines 23-27; page 5, lines 12-15. It is respectfully submitted that the claim amendments raise no new issues and would simplify issues for appeal. Favorable reconsideration of the application, as amended, is respectfully requested.

### I. REJECTIONS OF CLAIMS 1-19 UNDER 35 U.S.C. § 102(b)

Claims 1-19 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,328,701 ("Richmond"). Please enter the amendments submitted herewith. The amendments simplify issues and allow the matter to be resolved at this juncture. Withdrawal of the rejections is respectfully requested.

Independent claims 1 and 11 have been amended to further clarify pertinent features of the invention. Note that the claims define the irrigating solution using "consisting essentially of" transitional language. The effect of this recitation is to narrow the composition to those which do not contain an energy source (which previously could have been present) and also to specify that any electrolytes present to maintain physiological function are selected from  $\text{Na}^+$ ,  $\text{K}^+$ ,  $\text{Ca}^{2+}$  and  $\text{Cl}^-$ . It has also been made clear that the compositions are aqueous.

The amended independent claims are therefore novel over Richmond. The compositions of Richmond contain a nutrient source including at least one member of the citric acid cycle (see, column 2, lines 11-12; and claim 1 at column 4 of Richmond). The composition used in the

method of claim 1 and the solution of claim 11 are restricted to a specific combination of components which does not include the nutrient sources which are specified in Richmond.

Furthermore, it is respectfully submitted that the method of claim 1 and the irrigation solution of claim 11 are not obvious from the Richmond reference for at least the reasons set forth below. It is an essential requirement of Richmond that the composition contains a nutrient source including at least one member of the citric acid cycle. The combination of components of the Richmond reference is stated to represent a "balanced amount of compatible electrolytes and at least one compound from the citric acid cycle," and it is apparent that these components are considered necessary in order for the irrigating solution to function effectively although it is noted that there is no supporting data in Richmond, unlike the present invention.

By contrast, as will be apparent from the specification of the present invention, the narrowly defined composition of the present invention is effective in a laboratory experiment carried out on corneas obtained from New Zealand white rabbits (Examples 1 and 2). As stated in the application, these examples demonstrate that the composition of the invention supports endothelial function at least as well as BSS Plus, despite the absence of various components which are considered essential constituents in BSS Plus (see, page 10, lines 7-11 of the present application). Since the Richmond composition is considered as an alternative to BSS Plus (for example, see, column 1, line 65 - column 2, line 2), it also follows that the composition of the present invention provides function at least as good as those of Richmond. This could not have been predicted from Richmond, in which the presence of the nutrient source including at least one member of the citric acid cycle was considered to be essential. Without any motivation for those skilled in the art to remove this component, the composition of the present invention, and its method of use, would not have been obvious to those skilled in the art. Accordingly, it is submitted that the claimed invention is patentable over the cited art.

For at least the reasons set forth above, Richmond fails to teach or suggest the features recited in claims 1 and 11. Claims 2-10, and 12-19 dependent, either directly or indirectly, from one of claims 1 and 11 are also believed to be allowable for at least the same reasons set forth above in connection with the independent claims. Accordingly, withdrawal of the rejections to claims 1-19 is respectfully requested.

## II. CONCLUSION

Applicants believe that all pending claims are in condition for allowance, and respectfully requests a Notice of Allowance at an early date. If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 510-843-6200.

Respectfully submitted,  
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**APPENDIX -- VERSION WITH MARKINGS TO SHOW CHANGES MADE**

**IN THE CLAIMS:**

1. (Twice Amended) A method of irrigating the eye of a patient during surgery comprising supplying to the eye [a] an aqueous solution consisting essentially of a source of bicarbonate ions, a physiologically acceptable organic buffer which is an organic zwitterionic buffer having a buffering capacity within the range pH 6.8 to 8.0, and optionally a source of phosphate ions and/or source of electrolytes necessary to maintain physiological function [and/or an energy source] selected from Na<sup>+</sup>, K<sup>+</sup>, Ca<sup>2+</sup> and Cl<sup>-</sup>.

11. (Thrice Amended) An aqueous ocular irrigating solution for irrigating the eye during surgery consisting essentially of a source of bicarbonate ions, a physiologically acceptable organic buffer which is an organic zwitterionic buffer having a buffering capacity within the range pH 6.8 to 8.0, sources of electrolytes necessary to maintain physiological function and optionally a source of phosphate ions [and/or an energy source] selected from Na<sup>+</sup>, K<sup>+</sup>, Ca<sup>2+</sup> and Cl<sup>-</sup>, and wherein the bicarbonate source is present in the solution to give a bicarbonate concentration of from 10 to 50 mmol/l.